

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Robert A. Van Tassel	Examiner:	Vy Q. Bui
Serial No.:	10/656,647	Group Art Unit:	3773
Filing Date:	9/4/2003	Docket No.:	4056
Title	Filter Apparatus for Ostium of Left Atrial Appendage		

BRIEF ON APPEAL

Mail Stop Appeal Brief - Patents
Commissioner for Patents
Alexandria, VA 22313

Sir:

This Brief on Appeal is filed pursuant to the Notice of Appeal filed on August 12, 2009, and is an appeal from the Office Action mailed from the U.S. Patent and Trademark Office on March 12, 2009. The balance of this appeal is set forth under appropriate headings, as specified by 37 C.F.R. 41.37(c).

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I. REAL PARTY IN INTEREST

The real party in interest is Atritech Inc., the assignee of the entire right, title and interest in the subject application, by virtue of assignments recorded on July 28, 2006 at Reel 018026, Frame 0660, and on August 20, 2007 at Reel 019714, Frame 0631.

II. RELATED APPEALS AND INTERFERENCES

Appellant, the undersigned Attorney, and Assignee are not aware of any related appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

All claims have been cancelled save Claims 1-7 which are currently pending in this application. Claims 2-3 are withdrawn. Claim 7 stands finally rejected under Section 103. Claims 1, 4-6 are finally rejected under section 102. Claims 1, 4-7 are being appealed. A copy of the claims appears in the Appendix of this Brief.

IV. STATUS OF AMENDMENTS

Claims 1-7 have not been the subject of an amendment. Examiner has maintained the Section 102 and 103 rejections of the claims.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The Left Atrial Appendage is a closed and tubular shaped structure located high on the left atrium of a patient's heart. As part of the heart the atrial appendage moves. The purpose of the invention is to prevent clots forming in the atrial appendage from

being expelled from the atrial appendage and entering the general circulation where they are believed to enter the brain and cause strokes.

The Applicant's invention, simply stated, is a filter to be placed across the left atrial appendage of a patient. there are several embodiments of the invention shown, and most of the variations are directed to anchoring mechanisms or techniques. Since the heart is beating it is not a trivial problem keeping the device in place.

As stated on Page 1, Paragraph 0011 "The filtering membrane itself is permeable to permit blood flow across the membrane ". This is an important statement and distinguishes the invention from applied references. Later in that paragraph (0011) the natural process of infiltration is described. As set forth and as is well known in the art, the membrane supports tissue growth. This attribute is further discussed in Paragraph 0015, where it is acknowledged that this tissue growth occurs later. During the acute phase the porosity prevents hydraulic forces from building up behind the membrane and dislodging it which is described in Paragraph 0126 in more detail. In Paragraph 0122 representative materials for the membrane are enumerated and the required physical properties are set forth in Paragraph 0123 to 0123.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

In the final Office Action, Section 102 and 103 rejections were made to Claims 1 and 4-7.

The Examiner reasserts that the invention as claimed is anticipated or obvious in view of Lesh 6,152,144.

The Examiner's argument is simple. The Examiner notes correctly that the Lesh reference is also a plug for the left atrial appendage and it does discuss a pore size of the membrane spanning the ostium or opening of the left atrial appendage. The Examiner couples this acknowledged teaching of the Lesh reference with the argument that changing pore size in a membrane is a matter of obvious choice, or perhaps inherent in the Lesh disclosure.

VII. ARGUMENT

Section 102 Rejection

Anticipation requires that the claimed invention be present within the applied reference. There is no discussion in Lesh permitting the blood to flow back and forth across the membrane of Lesh, and the pore size is insufficient to allow such transfer of material. The Examiner notes that there is a wide range of pore size discussed in Lesh but it is quite important to note that the material described by Lesh is expanded PTFE and multiple layers of material are bonded together to form a laminate so that none of the holes actually communicates across the structure. If one were to take a material of Lesh and place water on it, the water would bead up and remain on the surface and not flow through the membrane. Since the filtration feature required by the claim is not present in Lesh, Lesh does not anticipate the invention.

Section 103 Rejection

Obviousness requires that one of ordinary skill could reach the claimed structure without the process of invention.

The Examiner treats the invention as a mere selection of appropriate pore size failing to recognize that the pore size of Lesh does not and cannot reach to a filtration membrane. In essence the mechanism of action in Lesh differs from the mechanism of action in Van Tassel. In Lesh, an impervious membrane is placed across the ostium while in Van Tassel a membrane is porous and permits fluid exchange. These differences are substantial because the membrane is across a structure that is beating along with the heart and can be expected to change in volume. As a consequence the filtration not only prevents the transfer of clot material but also eliminates the ability of pressure to build up behind the membrane and cause it to pop out of the LAA during a heartbeat. This is a problem unrecognized by Lesh and no structure within his application can be modified to supply the deficiency.

The membrane of Lesh has a pore size designed to promote the ingrowth of tissue after the device has been placed in a patient for some period of time, tissue grows over the device itself and the pore size selected by Lesh is optimized to promote that growth. This pore size is so small that blood cannot get across the membrane and as a consequence the Lesh membrane is totally impermeable to blood and blood clots.

To argue that pore size is immaterial or a matter of obvious choice would be similar to taking a position that one may substitute a fish net for a parachute and achieve the desired results of a gentle decent to the ground. Pore size matters when the sizes selected have entirely different functions.

VIII. REQUEST FOR RELIEF

Based on the above rationale, the Applicant has appealed the Examiner's final rejection of the pending claims. The Applicant respectfully solicits the Board

Respectfully submitted,

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IX. CLAIMS APPENDIX

1. (Original) A method of filtering the flow of blood between an atrium and a left atrial appendage of a patient comprising:

providing a filtering membrane having a permeable structure which allows blood to flow through the filtering membrane but substantially inhibits thrombus from passing therethrough, and a support structure attached to the filtering membrane configured to permanently engage a portion of an ostium and an interior wall of the left atrial appendage;

positioning the filtering membrane across the ostium by permanently engaging the portion of the interior wall of the left atrial appendage with the support structure; and

filtering blood flow through the ostium with the filtering membrane such that blood may flow through the filtering membrane while thrombus is substantially inhibited from passing therethrough.

2. (Original) The method defined in claim 1, wherein the support structure comprises a centering structure extending from the filtering membrane, and

wherein the positioning the filtering membrane comprises centering the filtering membrane over the ostium by passing the centering structure into the ostium.

3. (Original) The method as defined in claim 1, wherein the support structure comprises an anchor structure and a tether extending between the anchor structure and the filtering membrane, and

wherein positioning the filtering membrane further comprises piercing the wall of the left atrial appendage with the anchor structure.

4. (Original) The method as defined in claim 1, wherein the support structure comprises an expandable structure, and

wherein the positioning the filtering membrane further comprises expanding the expandable structure to engage an interior wall of the left atrial appendage.

5. (Original) The method as defined in claim 1, wherein the support structure comprises a substantially cylindrical configuration, and
wherein the positioning the filtering membrane further comprises expanding the support structure to engage the interior wall of the left atrial appendage.
6. (Original) The method as defined in claim 5, further comprising:
providing an expandable structure which is positioned within the support structure and which radially expands the support structure, and
wherein the positioning the filtering membrane further comprises expanding the expandable structure, thereby expanding the support structure.
7. (Original) The method as defined in claim 6, wherein the filtering membrane defines an opening therethrough, the method further comprising:
after expanding the support structure to engage the interior wall of the left atrial appendage, removing the expandable structure through the opening in the filtering membrane.

X. EVIDENCE APPENDIX

NONE

XI. RELATED PROCEEDINGS APPENDIX

NONE